K002708

NOV 2 8 2000

SECTION 9

510(k) SUMMARY

This 510(k) summary of safety and effectiveness for the KaVo Corund Handpiece 2013 is submitted in accordance with the requirements of SMDA 1990 and follows Office of Device Evaluation guidance concerning the organization and content of a 510(k) summary.

Applicant: KaVo America

Address: 340 East Main Street
Lake Zurich, IL 60045

Manufacturer: KaVo Dental GmbH
Bahnhofstr. 20
D-8847 Warthausen
Biberach
GERMANY

Contact Person: Mr. John Westermeier

Telephone: 847-550-6800
847-550-6825 (Fax)
800-323-8029

Preparation Date: August 2000
(of the Summary)

Device Name: KaVo Corund Handpiece 2013

Common Name: Airbrush

Classification: Airbrush (see: 21 CFR 872.6080)
Product Code: KOJ
Panel: 76

Predicate devices: Midwest AirTouch Tower; American Dental Technologies KCP 1000 PAC; Air Techniques AirDent II and AirDent II CS; Texas Airsonics Model 2000

Device description: The KaVo Corund Handpiece 2013 is an airbrush using aluminum oxide as an abrasive material.

Indications: The KaVo Corund Handpiece 2013 is intended for the:

preparation for fissure sealing by cleaning, opening, and extending the fissures;
creation of micro-mechanical retention for adhesive restorations on enamel and dentine with subsequent acid etch technique;
preparation of small carious defects;
removal of deep discolorations in the enamel;
cleaning and removal of adhesive residues from bridges, crowns, etc.; and,
preparation of adhesive surfaces of brackets.

KaVo proposes that the KaVo Corund Handpiece 2013 be labeled:

"CAUTION: Federal (US) law restricts the use of this device to licensed professionals."

Performance Data: None required. The claim of substantial equivalence is based on comparisons of specifications and indications and equivalent to its claimed predicates based on comparisons of specifications and indications.

CONCLUSION: Based on the information in the notification KaVo America believes that the Corund Handpiece 2013 is substantially equivalent to legally marketed predicates for the indications requested in the notification.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 2 8 2000

Mr. John Franz
President
KaVo America Corporation
340 East Main Street
Lake Zurich, Illinois 60045

Re: K002708
Trade Name: KaVo Corund Handpiece 2013
Regulatory Class: II
Product Code: KOJ
Dated: August 24, 2000
Received: August 30, 2000

Dear Mr. Franz:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531

through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SECTION 7

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K002708

Device Name: KaVo Corund Handpiece 2013

Indications for Use Statement:

The KaVo Corund Handpiece 2013 is intended for the:

preparation for fissure sealing by cleaning, opening, and extending the fissures;
creation of micro-mechanical retention for adhesive restorations on enamel and dentine with subsequent acid etch technique;
preparation of small carious defects;
removal of deep discolorations in the enamel;
cleaning and removal of adhesive residues from bridges, crowns, etc.; and,
preparation of adhesive surfaces of brackets.

KaVo proposes that the KaVo Corund Handpiece 2013 be labeled:

CAUTION: Federal (US) law restricts the use of this device to licensed professionals.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation

Prescription Use ___ OR Over-The Counter Use ___
(Per 21 CFR 801.109)

Susan Runner

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K002708